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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10 054,967	01 25 2002	Brent L. Kreider	1488 034000B	9197

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EXAMINER

KEMMERER, ELIZABETH

ART UNIT PAPER NUMBER

1646

DATE MAILED 05 22 2003

Please find below and or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10 054.967

Applicant(s)

KREIDER ET AL.

Examiner

Elizabeth C. Kemmerer, Ph.D.

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 41-230 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 41-68 and 70-230 is/are rejected.
- 7) ☒ Claim(s) 69 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 6
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group I in Paper No. 9 (11 April 2003) is acknowledged. Applicant's arguments are found to be persuasive, and thus the restriction requirement is withdrawn.

### ***Status of Application, Amendments, And/Or Claims***

The preliminary amendments of 25 January 2002 (Paper Nos. 3 and 4) have been entered in full. Claims 1-40 are canceled. Claims 41-230 are under examination.

The request to change the inventorship (Paper No. 3, 25 January 2002) has been granted. The inventors of record are: Brent L. Kreider, Steven M. Ruben and Henrik S. Olsen.

### ***Drawings***

The formal drawings were received on 25 January 2002. These drawings are accepted.

### ***35 U.S.C. § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 136-230 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 136-230 were submitted with a preliminary amendment received 25 January 2002 (Paper No. 3). Applicant indicates that support for the new claims can be found in original claim 37. However, original claim 37 is directed to a method for activating or mobilizing basophils, whereas new claims 136-230 are directed to methods of *inhibiting* the activation or mobilization of basophils. Also, original claim 37 is directed to the administration of peptides other than those recited in new claims 136-230. Applicant also points to the specification at pp. 8, 35-39, 28 and 31. However, these pages merely provide support for the specific peptides recited in the claims and the general concept of antagonists. The specification as originally filed does not disclose the concept of inhibiting the activation or mobilization of basophils using the peptides recited in the claims. The concept is not specifically disclosed, and does not flow naturally from the specification.

Claims 41-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed invention wherein a polypeptide consisting of the amino acid sequence shown in SEQ ID NO: 48 is administered, does not reasonably provide enablement for administration of any other polypeptides to

inhibit the activation or mobilization of eosinophils. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are directed to methods of inhibiting the activation or mobilization of eosinophils in an individual comprising administering to the individual a therapeutically effective amount of a polypeptide consisting of an amino acid sequence shown in any one of SEQ ID NOS: 23-114. The specification discloses that a specific deletion mutant of the chemokine  $\beta$ -6 consisting of the amino acid sequence shown in SEQ ID NO: 2, namely,  $\Delta$ C1 $\Delta$ N3 (HG00606) inhibited chemotaxis of eosinophils *in vitro* (pp. 112-113). This mutant corresponds to the polypeptide consisting of the amino acid sequence 4 to 73 of the full length chemokine  $\beta$ -6 of SEQ ID NO: 2. The deletion mutant also corresponds to the polypeptide consisting of the amino acid sequence shown in SEQ ID NO: 48. Interestingly, a deletion mutant that differs from SEQ ID NO: 48 by only 3 amino acid residues actually enhanced chemotaxis of eosinophils (deletion mutant  $\Delta$ C1, consisting of amino acid residues 1-73 of the full length chemokine  $\beta$ -6 of SEQ ID NO: 2). The specification provides no guidance regarding what sequences other than those three amino acid residues can be deleted without loss or change of activity. The state of the art also shows that even minor alteration of the sequence of a protein in this class results in an unpredictable change in activity. See Kopchick et al. (U.S. Patent 5,350,836), who disclose several antagonists of vertebrate growth hormone that differ from naturally occurring growth hormone by a single amino acid (column 2, lines 37-48).

Due to the large quantity of experimentation necessary to determine which polypeptides other than the one consisting of the amigo acid sequence of SEQ ID NO: 48 would have the required activity of inhibiting activation or mobilization of eosinophils, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to the same, the complex nature of the invention, the state of the prior art evidencing the unpredictability of even minor sequence alterations on protein functions in this protein class, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claims 44-68 and 70-135 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The basis of this rejection is the same as that given in the scope of enablement rejection for claims 41-43 above. Specifically, the specification is not enabling for the claimed methods using any peptide but the one shown in SE QID NO: 48.

### ***Claim Objections***

Claim 69 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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**Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (703) 308-2673. The examiner can normally be reached on Mon. - Thurs., 6:30 to 4:00, and alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler, Ph.D. can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

*Elizabeth C. Kemmerer*

ELIZABETH C. KEMMERER  
EXAMINER

ECK  
May 19, 2003